



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MANTHORPE *et al.*

Appl. No. 09/839,574

Filed: April 23, 2001

For: **Compositions and Methods for *in vivo* Delivery of Polynucleotide-Based Therapeutics**

Confirmation No.: 1437

Art Unit: 1635

Examiner: Schnizer, R.A.

Atty. Docket: 1530.0180002/EKS/EJH

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**Declaration of
Jukka Hartikka, Jennifer Meek, and Marston Manthorpe
Under 37 C.F.R. ' 1.132**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

We, Jukka Hartikka, Jennifer Meek, and Marston Manthorpe, hereby declare and state as follows:

1. We are three of the four named inventors of the captioned application.
2. We, together with V. Bozoukova, D. Jones, R. Mahajan, M.K. Wloch, M. Sawdey, C. Buchner, L. Sukhu, K.M. Barnhart, A.M. Abai, and N. Shen, co-authored the paper entitled "Sodium phosphate enhances plasmid DNA expression *in vivo*," published in *Gene Therapy* 7: 1171-1182 (2000) ("Hartikka *et al.*"), which has been cited by the Examiner in the captioned application as allegedly teaching or suggesting the "salt" element required in the pending claims.
3. The contributions of the named authors of the paper are as follows:
4. V. Bozoukova is employed in the Department of Cell Biology at Vical Incorporated. While under the direction of J. Hartikka, this individual carried out the

osmolarity studies described on page 1173, at column 2, of Hartikka *et al.* Also under the direction of J. Hartikka, V. Bozoukova conducted the experiments shown in Figure 3, as well as the experiments shown in Figure 4. Lastly, V. Bozoukova, together with M.K. Wloch, conducted the confirmatory experiments shown in Figure 6.

5. D. Jones and R. Mahajan were in the Department of Molecular Biology at Vical Incorporated. These individuals, at our suggestion conducted the confirmatory alkaline phosphatase ("SEAP") experiments shown in Figure 5.

6. M. Sawdey is in the Department of Cell Biology at Vical Incorporated. Following the discovery by us that certain salt vehicles enhance plasmid DNA expression, this individual proposed a mechanistic rationale for the observed enhancement and conducted the experiments shown in Figure 9 to examine possible mechanisms responsible for the observed enhancement. M. Sawdey, together with K.M. Barnhart, also constructed the various test plasmids used in the experiments described in Hartikka *et al.*

7. C. Buchner is in the Department of Cell Biology at Vical Incorporated. This individual, together with and under the direction of J. Hartikka, conducted the experiments shown in Figure 7.

8. A.M. Abai is in the Department of Molecular Biology at Vical Incorporated. This individual, at our suggestion, conducted the confirmatory proinsulin experiments shown in Figure 5.

9. N. Shen is in the Department of Pharmaceutical Development at Vical Incorporated. This individual, under our direction, purified the various test plasmids and provided general support for our work.

10. L. Sukhu (Loretta Sukhu) is in the Department of Cell Biology at Vical Incorporated. Loretta Sukhu conducted the confirmatory experiments shown in Figure 8.

11. Other than ourselves, none of the co-authors, except Loretta Sukhu, made any inventive contribution to the invention claimed in the captioned application. While Loretta Sukhu contributed to the conception of certain other elements required in the pending claims, none of our co-authors in Hartikka *et al.*, including Loretta Sukhu, contributed to the conception of the "salt" element.

12. We further declare that all statements made herein of our own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

05 Sept 03
Date

09-05-03
Date

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Date

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